

UNSWORN DECLARATION UNDER PENALTY OF PERJURY

I, Dr. Eric Alicea-Martínez, of legal age, do solemnly swear under penalty of perjury:

1. I am employed as the Medical Director for Ciales Primary Health Care Services, Inc., (PRYMED). I have held this position since February 11, 1992.
2. Dr. Hernan Fuentes-Figueroa, who has been named as a defendant in the following complaint Manuel Olivera-Pagan, et al. v. Manati Medical Center, Inc., et al., which has been filed in the United States District Court for the District of Puerto Rico, Civil No. 14-1553 (FAB), was employed at Ciales Primary Health Care Services, Inc., from April 18, 2006 to September 30, 2010.
3. Beginning January 1, 2009, the United States Department of Health and Human Services deemed Ciales Primary Health Care Services, Inc., eligible for Federal Tort Claims Act ("FTCA") coverage pursuant to the Federally Supported Health Centers Assistance Act ("FSHCAA" or "the Act") (42 U.S.C. § 233(g)-(n)) and that coverage has continued without interruption since that time.
4. Dr. Hernan Fuentes-Figueroa was acting within the scope of Ciales Primary Health Care Services, Inc., scope of coverage at the time he delivered the Plaintiff's infant at Manati Medical Center, therefore, any medical services rendered by Dr. Hernan Fuentes-Figueroa during the time alleged in the complaint at Manati Medical Center were in his capacity as a Ciales Primary Health Care deemed employee.
5. Dr. Hernan Fuentes-Figueroa billed privately for delivery services rendered to plaintiff Daisy DeJesus Miranda at Manati Medical Center as permissible under the Federal Tort Claims Policy Manual ("FTCA Manual") annexed hereto as Exhibit A, which provides health centers with guidelines for alternate billing arrangements for services provided by health center employees or contractors to health center patients.
6. The FTCA Manual provides under Section I, Eligibility and Coverage, (E) Coverage under Alternate Billing Arrangements, "if an employee or contract provider, meeting all other requirements for coverage under FTCA, bills for a service delivered at a location not identified as a covered entity site within its approved Federal section 330 scope of project, FTCA coverage will apply".
7. I declare the foregoing is true and correct to the best of my knowledge and belief, and is given under penalty of perjury pursuant to 28 U.S.C. § 1746.

In Ciales, Puerto Rico, this 9th day of January, 2015.



Dr. Eric Alicea-Martínez
Medical Director
PRYMED

EXHIBIT A



U.S. Department of Health and Human Services
Health Resources and Services Administration

FEDERAL TORT CLAIMS ACT

Health Center Policy Manual

(Supersedes PIN 2011-01)

Updated 7/21/2014

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FEDERAL TORT CLAIMS ACT Policy Manual

INTRODUCTION

The Federally Supported Health Centers Assistance Acts (FSHCAA) of 1992 (Pub. L. 102-501) and 1995 (Pub. L. 104-73) extend Federal Tort Claims Act (FTCA) protections under 28 U.S.C. 1346(b), 2401(b), and 2679-81 to eligible health centers^[1] funded under the Health Center Program, section 330 of the Public Health Service (PHS) Act (42 U.S.C. 254b), as amended. Eligibility for FTCA protections has been extended to:

- Community Health Centers (CHC), funded under section 330(e);
- Migrant Health Centers (MHC), funded under section 330(g);
- Health Care for the Homeless (HCH) Health Centers, funded under section 330(h); and
- Public Housing Primary Care (PHPC) Health Centers, funded under section 330(i).

A final rule was published on May 15, 1995 and was codified in Title 42, Section 6.6 of the Code of Federal Regulations (CFR). Further program guidance was published on September 25, 1995 (60 Federal Register 49417) (<https://federalregister.gov/a/95-23601>). The program is more commonly called the Health Center FTCA Medical Malpractice Program.

The intent of the Health Center FTCA Medical Malpractice Program is to increase the availability of funds to health centers to provide primary health care services. By reducing or eliminating health centers' malpractice insurance premiums, more health center dollars are available for:

- Increasing the number of patients served;
- Increasing enabling services like case management and health education;
- Reducing financial, geographic, and cultural/linguistic barriers to care; and
- Implementing and expanding programs such as quality improvement/assurance and risk management and other appropriate section 330 –funded activities.

FSHCAA provides that certain persons, referred to here as covered individuals (i.e., governing board members, officers, employees, and certain individual contractors) of FTCA covered entities (e.g., health centers that receive section 330 funds and have been approved for coverage or “deemed” as employees of the Public Health Service by the Secretary) be treated as PHS employees for purposes of medical malpractice liability coverage. Covered activities are acts or omissions in the performance of medical, surgical, dental, or related functions resulting in personal injury, including death, and occurring within the scope of employment. Further discussion of “scope of employment” is set forth below.

Under FSHCAA, these covered individuals have medical malpractice protection for covered activities. Covered activities include those activities that:

- Are approved within each individual's scope deemed of employment (this term includes activities within an applicable individual contract for services with the health center);
- Are within the scope of the approved Federal section 330 grant project of the deemed health center; and
- Take place during the provision of services to health center patients and, in certain circumstances, to non-health center patients.

Under FTCA, parties claiming to be injured by medical malpractice must file administrative claims with the appropriate agency of the Federal government before filing suit. FTCA litigation must be filed in Federal district court. Further information regarding the filing of FTCA claims or litigation is available in **Section II: Claims and Lawsuits** and in federal law.

FTCA coverage for entities receiving section 330 funds is not assured from year to year. Health centers must apply annually to Health Resources and Services Administration/Bureau of Primary Health Care (HRSA/BPHC) to be

deemed employees of the PHS, with associated FTCA coverage for the organization and, by extension, for their covered individuals. Each year, Health Centers are approved after they demonstrate that they meet the requirements outlined in section A.2 of this document and all other FTCA Program requirements.

This FTCA Policy Manual is the primary policy source for information on FTCA for Health Center Program grantees and related stakeholders. It is divided into three sections: Section I: Eligibility and Coverage; Section II: Claims and Lawsuits; and Section III: Appendix. It will be updated as new policy and program guidance are issued. Please note, however, that when FTCA matters become the subject of litigation, the Department of Justice and the federal courts may assume significant roles in certifying or determining whether or not a given activity falls within the scope of employment, for purposes of FTCA coverage.

SECTION I. ELIGIBILITY AND COVERAGE

A. Covered Entities

A.1 Eligibility for Deeming

An entity receiving funds under Section 330, also referred to as a Health Center Program grantee or subgrantee/subrecipient, must be deemed as an employee of the Public Health Service (PHS) by the Secretary of Health and Human Services (Secretary) [\[2\]](#) in order for the entity, as well as certain other individuals identified by the statute, to be covered under FTCA. [\[3\]](#) When a health center grantee or subrecipient is deemed, it is called a covered entity for purposes of this Manual. Grantees eligible to be deemed are:

- Community Health Centers (CHC), funded under section 330(e);
- Migrant Health Centers (MHC), funded under section 330(g);
- Health Care for the Homeless (HCH) Health Centers, funded under section 330(h); and
- Public Housing Primary Care (PHPC) Health Centers, funded under section 330(i).

Subrecipients eligible for FTCA coverage are entities that receive a grant or a contract from a covered entity to provide the full range of health services on behalf of the covered entity. [\[4\]](#)

A.2 Application for Deeming

As required by sections 224(g)(1)(D) and 224(h) of the PHS Act, to be deemed, a Health Center Program grantee or subrecipient must complete an application (see **Section G: Deeming Application Process**) in the specified form. [\[5\]](#) The application must document that the entity has met program requirements for FTCA coverage. To be deemed, a grantee or subrecipient must complete an application that demonstrates that it:

- Has implemented appropriate policies and procedures to reduce the risk of malpractice and the risk of lawsuits arising out of any health or health related functions performed by the covered entity;
- Has implemented a system whereby professional credentials, references, claims history, fitness, professional review organization findings, and licensure status of its physicians and other licensed or certified health care providers are reviewed and verified and, where necessary, has obtained the permission from these individuals to gain access to this information; [\[6\]](#)
- Has no history of claims having been filed against the United States as a result of the application of FSHCAA to the entity or its covered individuals, or, if such a history exists, has fully cooperated with the Department of Justice in defending any such claims and either has taken, or will take, any necessary corrective steps to assure against such claims in the future; and
- Will fully cooperate with the Attorney General and the Federal Government in providing the necessary information related to the claim.

A.3 Special Circumstance: Indemnification of Other Entities

Many organizations and entities with which health centers contract, insist that hold harmless or indemnification clauses be incorporated into contracts with provider organizations. However, FTCA coverage does not extend to indemnification of those other entities and organizations.^[7] The covered entity is responsible for any losses incurred as a result of indemnification clauses in contracts. Therefore, to the extent possible, the covered entity should have indemnification clauses removed from the contract or obtain appropriate private insurance coverage for any indemnification claims that may arise.

B. Covered Individuals

FSHCAA extends FTCA liability protection for medical malpractice to any eligible officer, governing board member, employee, or qualified contractor of a covered entity, subject to the requirements of the PHS Act (including subsection 224(i)).^[8] For the purposes of the FTCA Policy Manual, the term covered individuals applies to all such individuals. FTCA coverage is afforded to covered individuals by virtue of their working relationship with the covered entity. Covered individuals are ordinarily deemed to be Public Health Service (PHS) employees by operation of a deeming determination regarding the covered entity, combined with proof of satisfaction of the permissible relationship under FSHCAA, such as officer, governing board member, health center employee, or qualified contractor.

B.1 Governing Board Members and Officers

As is the case for all covered individuals, the covered entity's governing board members and officers are covered under the FTCA only for medical malpractice, as described in this Manual. FTCA should not be considered by health centers as a substitute or replacement for directors' and officers' insurance.

B.2 Employees

Employees are covered for medical malpractice under FSHCAA and the FTCA whether they work full-time or part-time for the covered entity. HRSA/BPHC utilizes the Internal Revenue Service (IRS) definition to establish who is an employee. To be considered as an employee by the IRS, the individual must receive a salary from the covered entity on a regular basis with applicable taxes and benefits deducted along with coverage for unemployment compensation in most cases. The covered entity should issue a W-2 form for an employee to be a covered individual.

B.3 Contractors

Licensed or certified individual health care provider contractors working full-time (on average at least 32.5 hours per week for the health center for the period of the contract) are covered under FSHCAA and the FTCA. These time requirements do not apply to individual contractor providers in the fields of family practice, general internal medicine, general pediatrics, obstetrics and gynecology, who therefore are covered under FSHCAA and the FTCA even if they provide services to the covered entity on a part-time basis.

HRSA/BPHC utilizes IRS definitions to differentiate contractors and employees. Typically, a covered entity will issue a Form 1099 to an individual who is a contractor.

To ensure FTCA coverage for contract providers, there should be a documented contractual relationship (i.e., a written contract for the provision of health services) between the covered entity and the individual provider. In addition, compensation that arises from this contract, such as contracted wages, should be paid by the covered entity directly to the individual contract provider. A contract between a covered entity and a provider's corporation does not confer FTCA coverage on the provider. Services provided strictly pursuant to a contract between a covered entity and any corporation, including eponymous professional corporations (defined as a professional corporation to which one has given one's name, e.g., John Doe, LLC, and consisting of only one health care provider), are not covered under FSHCAA and the FTCA.

B.4 FTCA Coverage/Protection for Covered individuals

FTCA malpractice immunity is similar to an occurrence insurance policy. Occurrence coverage is a form of insurance that provides coverage for actions and omissions that take place during the time that the policy is in

effect, regardless of when the claim is filed. This is in contrast to a “claims made policy” that covers the individual for those claims that are filed during the term of the policy.

A covered individual of a covered entity who leaves the covered entity is protected for all covered activities resulting in allegations of medical malpractice that occurred while he/she was working as an officer, governing board member, employee, or qualified contractor of the covered entity. This protection is contingent upon the covered individual meeting all of the requirements of FSHCAA. Since FTCA coverage is analogous to an occurrence form of malpractice insurance, covered entities do not need to purchase tail coverage for individuals whose activities were protected by the FSHCAA for actions occurring after they are no longer employed by or contracted with the covered entity.

B.5 Exceptions: Non-Covered Individuals

Individuals who do not meet the statutory requirements for covered individuals, as described above, are not covered under FSHCAA and the FTCA. In the case of non-covered individuals, such as volunteer physicians and part-time (i.e., averaging less than 32.5 hours) contract dentists providing services within the scope of the approved Federal section 330 grant project, the covered entity remains covered, while the individual is not.

B.5 Example

Volunteers and AmeriCorps members who are neither employees nor contractors of the covered entity are non-covered individuals under FSHCAA and are, therefore, not eligible for FTCA coverage.

While it can be anticipated that covered entities will receive numerous offers of and requests for volunteer assistance during emergencies (see **Section I: F. FTCA Coverage When Responding to Emergency Events**), covered entities should be aware that volunteers do not meet the statutory definition for FTCA coverage under FSHCAA.

It is possible that a volunteer might qualify for immunity or limited liability under State or Federal charitable immunity and limited liability statutes, such as the Federal Volunteer Protection Act of 1997, or under Federal provisions related to the National Disaster Medical System (section 2811 of the PHS Act). However, these laws present a different form and mechanism for liability protection than that offered by the FTCA. Health centers should carefully consider the scope and limitations of such protections.

C. Covered Activities

FTCA coverage is restricted to acts or omissions of a covered entity that are within the scope of employment of a covered individual. For otherwise qualified individual contractors, the term “scope of employment” includes performance under an applicable individual contract. For actions to be within the scope of employment, and therefore to be covered activities, they must:

- Be within the approved scope of the project, including sites, services, and other activities and locations as defined in PIN 2008-01: Defining Scope of Project and Policy for Requesting Changes available online at <http://bphc.hrsa.gov/policiesregulations/policies/pin200801.html> (relevant forms are 5-A, 5-B, and 5-C);
- Be within the requirements of the job description, contract for services, and/or duties required by the covered entity; and
- Occur during the provision of services to the covered entity’s patients and, in certain circumstances, to non-health center patients.

It is the full responsibility of the covered entity to maintain current records for all covered individuals and any sites and schedules that may be relevant to their FTCA coverage. HRSA/BPHC does not maintain such records. In the case of a claim, a coverage determination depends upon verification that the individual was employed by or contracted with the covered entity at the time of the incident (see **Section II: Claims and Lawsuits**). It also depends upon verification that all statutory requirements of FSHCAA and the FTCA have been met and that the covered individuals and covered entity have complied with all FTCA requirements such as providing health care services within the approved scope of project and within the scope of deemed employment. It is important to

note that FTCA may still cover the entity for claims arising from covered activities if the activity was carried out by a non-covered individual. Lack of individual coverage, by itself, will not necessarily negate the health center's coverage as the covered entity.

C.1 Scope of Project

As noted above, FTCA coverage is limited to the performance of medical, surgical, dental, or related functions within the scope of the approved Federal section 330 grant project, which includes sites, services, and other activities or locations, as defined in the covered entity's grant application and any subsequently approved change in scope requests. FTCA coverage for new services and sites is dependent on HRSA/BPHC approval of a change in the scope of the project.

A request for a change in scope should be submitted to HRSA/BPHC for approval. Consult <http://bphc.hrsa.gov/about/requirements/scope/index.html> for policies related to a health center's scope of project. An accurate and detailed account of the scope should be clearly documented in the event of a claim to verify that the activity in question is within the scope of project and, therefore, where medical, surgical, dental, or related functions, is covered under FSHCAA and the FTCA.

C.2 Scope of Employment

For otherwise qualified individual contractors, the statutory phrase, "scope of employment," as used throughout this document, includes performance under an applicable individual contract.

All covered individuals, including employees, contractors, officers, and directors, should have current, written job/position descriptions that delineate the duties that each individual currently performs on behalf of the covered entity. Similarly, the content of the job/position description should comply with scope of employment, licensure, and certification requirements. Since FTCA matters may become the subject of litigation, these job descriptions may play a key role in demonstrating scope of employment and resultant FTCA coverage, as determined by the Department of Justice and the federal courts.

For a covered individual, the job/position description should specify the type of services to be provided and the location where these services will be provided. Documentation of services and sites/locations in the job description, including cross-coverage agreements, should be of sufficient detail to provide clarity in determining if the individual in question was acting within the scope of his employment with the covered entity.

Duties as outlined in a job/position description should align with the type of services an individual provides and where he/she provides them, as reflected in employment agreements, contracts for services, and approved services and service sites. Consistency in these areas will assist in determining that activities are within the scope of employment and therefore covered under FSHCAA and the FTCA.

Please note, moonlighting is defined as engaging in professional activities outside of covered entity employment responsibilities and is not within the covered entity's approved scope of project. Therefore, neither the covered entity nor the moonlighting provider receives FTCA coverage for moonlighting activities.

C.3 Provision of Services to Health Center Patients

To meet the FTCA requirement of providing services to health center patients, a patient-provider relationship must be established. For the purposes of FSHCAA/FTCA coverage, the patient-provider relationship is established when:

- Individuals access care for initial or follow-up visits at approved sites that are owned or operated by the covered entity;
- Individuals access care at approved sites even if they are not permanent residents of the service area or may only be receiving care temporarily; or
- Health center triage services are provided by telephone or in person, even when the patient is not yet registered with the covered entity but is intended to be registered.

C.3 Example

A patient not previously known to the health center calls complaining of nausea and is given an appointment for the next day. In the interim, the patient dies from a myocardial infarction and the family alleges poor triage by the covered entity's staff. Even though there may be no formal medical record of a patient encounter, the patient-provider relationship is established by demonstrating the relevant events of triaging and making appointments for medical care. These are health related functions that clearly fit within the scope of health center activities.

C.4 Covered Services to Non-Health Center Patients

FSHCAA and 42 CFR section 6.6(d) authorize FTCA coverage for services to non-health center patients in certain situations. FTCA Program regulatory amendments published on September 23, 2013 (78 Federal Register 58202) (September 2013 FRN) incorporate, clarify, and add to the situations identified in the September 1995 Notice. The September 2013 FRN, which amended 42 CFR 6.6(e), continues to provide notice that activities that fit squarely within the listed examples are approved for FTCA coverage under 42 CFR section 6.6(d) and section 224(g)(1)(B)(ii), as long as there is compliance with all other coverage requirements under FSHCAA. As indicated by the September 2013 FRN, if any element of an activity or arrangement does not fit squarely into the examples listed within the Notice (repeated below) for non-health center patients, the covered entity should request a particularized determination of coverage.

The activities described by these examples are as follows:

C.4 Examples of Covered Services to Non-Health Center Patients

Community-Wide Intervention School-Based Clinics - Health center primary and preventive health care services at a facility located in a school or on school grounds. The covered entity has a written affiliation agreement with the school.

School-Linked Clinics - Health center primary and preventive health care services, at a site not located on school grounds, to students of one or more schools. The covered entity has a written affiliation agreement with each school.

Health Fairs - On behalf of the health center, health center staff conduct or participate in an event to attract community members for purposes of performing health assessments. Such events may be held in the health center, outside on its grounds, or elsewhere in the community.

Immunization Campaigns - On behalf of the health center, health center staff conduct or participate in an event to immunize individuals against infectious illnesses. The event may be held at the health center, schools, or elsewhere in the community.

Migrant Camp Outreach - Health center staff travel to a migrant farm worker residence camp to conduct intake screening to determine those in need of clinic services. Health care services may be provided at the time of the intake activity or during subsequent clinic staff visits to the camp.

Homeless Outreach - Health center staff travel to a shelter for homeless persons, or a street location where homeless persons congregate, to conduct intake screening to determine those in need of clinic services. Health care services may be provided at the time of the intake activity or during subsequent clinic staff visits to that location.

Hospital-Related Activities - Periodic hospital call or hospital emergency room coverage, as required by the hospital as a condition for obtaining hospital admitting privileges. There must be documentation for the particular covered individual that this coverage is a condition of employment at the covered entity.

Coverage-Related Activities - As part of a health center's arrangement with local community providers for after-hours coverage of its patients, the covered entity's providers are required, by their employment contract, to provide periodic or occasional cross-coverage for patients of these providers.

Coverage in Certain Individual Emergencies - A health center provider is providing or undertaking to provide covered services to a health center patient within the approved scope of project of the center, or to an individual who is not a patient of the health center under the conditions set forth in this rule, when the provider is then asked, called upon, or undertakes, at or near that location and as the result of a non-health center patient's emergency situation, to temporarily treat or assist in treating that non-health center patient. In addition to any other documentation required for the original services, the health center must have documentation (such as employee manual provisions, health center bylaws, or an employee contract) that the provision of individual emergency treatment, when the practitioner is already providing or undertaking to provide covered services, is a condition of employment at the health center.

Acts and omissions related to services provided to individuals who are not patients of a covered entity will be covered if HRSA/BPHC has approved an application in the form and manner prescribed by HRSA/BPHC below for a particularized determination of FTCA coverage. HRSA/BPHC does not utilize particularized determinations to provide advisory opinions or to address coverage arrangements concerning services provided to existing health center patients.

The application for a particularized determination must provide sufficient information for HRSA/BPHC to determine if:

1. The provision of the services to non-health center patients will benefit patients of the covered entity and general populations that could be served by the covered entity through community-wide intervention efforts within the communities served by such entity;
2. The provision of the services to non-health center patients facilitates the provision of services to patients of the covered entity; or
3. Such services are otherwise required to be provided to non-health center patients under an employment contract or similar arrangement between the covered entity and the covered individual.

Accordingly, a request for a particularized determination of FTCA coverage must include sufficient detail to determine:

1. What services are provided;
2. Who provides the services;
3. Where the services are provided;
4. Why covered entity personnel are needed to provide such services; and
5. How these services benefit the patients of the covered entity.

The request for particularized determination must also provide a narrative explanation, signed by the Chief Executive Officer of the covered entity, setting forth how the request satisfies the criteria listed above. Job descriptions/positions and other relevant agreements or arrangements must be attached with the request to show how the covered entity will implement the activity for which FTCA coverage is sought. Please send all particularized determination applications or questions to ftcapd@hrsa.gov.

C.5 Additional Activities

As discussed above, FTCA coverage is restricted to acts or omissions of a covered entity. The following describes how certain off-site activities may properly be conducted on behalf of a covered entity.

C.5.1 Continuity of care

A covered individual may follow a covered entity's patient to a local non-health center site in order to maintain continuity of care, if the service provided at the non-health center site is within the covered entity's scope of project and the covered individual's scope of employment for the purpose of FTCA coverage.

C.5.1 Example

The provision of local inpatient hospital care to a covered entity's patients is considered part of the continuity of care of the patient and is covered by FTCA if the service provided at the local hospital is within the covered entity's scope of project and the covered individual's scope of employment. These arrangements, including location information, are best documented in an agreement with the non-health center entity, in the covered individual's employment agreement or individual contract, and in other appropriate health center records (e.g., job/position description).

C.5.2 Supervision

Supervision of non-health center staff by a covered individual is a covered activity if the service performed by the supervisee is (1) for the covered entity's patients (and, in certain circumstances, those addressed in section C.4, for non-health center patients), (2) is within the scope of project of the covered entity, and (3) is within the scope of employment of the covered individual. However, the non-health center staff being supervised by the covered individual are not covered by FTCA.

C.5.2 Examples

Supervision of Students and Medical Residents - Time spent by covered individuals in non-health center facilities such as hospitals supervising the care provided by students or medical residents to non-health center patients is covered only if (a) hospital call or emergency room coverage is required by the hospital as a condition of obtaining hospital admitting privileges and is in the covered entity's employment contract documentation, or (b) a particularized determination of FTCA coverage has been obtained from HRSA/BPHC. Such hospital call or emergency coverage must be within the scope of project of the covered entity and scope of employment of the covered individual. Providers who voluntarily take hospital call or emergency room coverage not required by the hospital as a condition of obtaining admitting privileges and who are not providing such services within the scope of a HRSA/BPHC particularized determination of coverage are not covered by FTCA.

Obstetrical Supervision - The supervision by a covered entity obstetrician of hospital staff during the delivery of a covered entity's patient is covered by FTCA when the care to the covered entity patient is a covered activity within the covered entity's approved scope of project and is within the scope of employment of the covered individual.

C.5.3 Teaching activities

Teaching activities, including, for example, the teaching of medical students, medical residents, and nursing students within facilities operated by a covered entity, qualify for FTCA coverage if the services provided or the medical or dental services being taught by the preceptor, including monitoring and oversight of services provided by the student, are within the scope of project of the covered entity and the scope of employment of the covered individual with the covered entity. The covered entity and the employed teaching provider (i.e., the covered individual) are covered by FTCA in this instance. The student or resident is not covered by FTCA unless he also is a covered individual in his own right. Except as described above, covered entity providers are not covered when supervising care provided by students and residents to non-health center patients in non-health center facilities.

C.5.4 Activities under other grant funding

FTCA coverage extends to services supported by funds provided through other HRSA grant funding if these services are within the approved scope of project of the covered entity and scope of employment of the covered individual with the covered entity. For example, services supported with funds under Ryan White Part C qualify for FTCA coverage if those activities are part of the approved scope of the covered entity's section 330 project. As such, revenues and expenses of the other HRSA grant program must be part of the covered entity's total section 330 grant budget.

C.5.5 Clinical research

Clinical research in the context of patient care, conducted by covered individuals with covered entity patients, qualifies for FTCA coverage if it is within the approved scope of project of the covered entity and scope of employment of the covered individual with the covered entity. Research to the extent that it involves non-health center patients is not covered by FTCA.

C.5.5 Example

A covered entity provider joins an international clinical research trial that compares two pharmacotherapy strategies to control hypertension using covered entity patients with the approval of the covered entity and patients involved. The individual and entity would be covered if participation in the study is incident to the medical treatment of the covered entity patients. The individual would not be covered for treatment of non-health center patients as part of the protocol.

C.5.6 Assisting with community events

Assisting with community events is a covered activity only if services provided at the events are included within the covered entity's scope of the approved Federal section 330 grant project with the covered entity.

C.5.6 Example

A covered entity provider who is a covered individual serves on the sidelines at local high school football games in the event that health care is needed by a student. This activity is covered under FTCA as a school-based or school-linked health program if the activity is part of the covered individual's scope of employment with the covered entity and if such services are within the covered entity's approved scope of project. For FTCA coverage to apply under the September 1995 Notice, the covered entity must have a written agreement in place for this activity.

D. Third Party Acceptance of Coverage and Verification of Coverage

D.1 Verification of FTCA Coverage

There may be instances where a covered individual will need to show proof of FTCA coverage. FTCA coverage applies to the individual provider by virtue of employment or certain contractual relationships with the covered entity (see **Section I: B. Covered Individuals**). Third parties such as hospitals and managed care organizations may request verification of FTCA coverage for individual providers from HRSA/BPHC. The Notice of Deeming Action (NDA) may be utilized as confirmation of medical malpractice coverage for both health centers and their covered individuals. The NDA, along with documentation confirming employment or contractor status with the deemed entity, may be used to show liability coverage for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions by PHS employees while acting within the scope of such employment.

Health Centers can access the NDA via HRSA's Electronic Handbook (EHB) by following the steps indicated below:

- Login to HRSA EHBs at <https://grants.hrsa.gov/webInternal/Login.asp>.
- Choose "View Portfolio" and "Open Grantee Handbook".
- Ensure that you open the H80 Grantee Handbook.
- If you have the required privileges (assigned by the Project Director), you can see a link to the "FTCA Program" under the "Other" section of the H80 Grantee Handbook.
- Choose the "FTCA Program" and select "Work on my FTCA applications".
- Choose the "NDA" link to view the NDA.
- Click on the "Print" button to print the page to a PDF file.

In some cases, third parties may not accept the NDA as valid proof of verification. In those limited situations, HRSA can provide additional special verification upon request. Health centers should submit requests to HRSA for such additional documentation only if the third party declines to accept the NDA as verification.

D.2 Acceptance of FTCA by Hospitals and Managed Care Plans

Section 224 of the PHS Act provides that a covered individual cannot be denied hospital admitting privileges solely because the individual's malpractice protection is provided by FTCA, so long as the appropriate professional qualifications and agreement to abide by the policies and bylaws of the hospital are met. FSHCAA provides that managed care plans, including health maintenance organizations and similar entities, must accept FTCA coverage

as meeting whatever malpractice insurance coverage requirements they may have for contracting providers, and that hospitals or managed care plans that fail to comply with these provisions will be in jeopardy of losing their ability to collect payment under Medicare and Medicaid.

In situations where a hospital, managed care organization, or other entity refuses to accept FTCA coverage as meeting any requirement for malpractice liability protection, a covered entity should immediately contact HRSA/BPHC. HRSA/BPHC will contact those entities directly in an effort to resolve the issue. If necessary, other resources will be engaged to achieve resolution.

E. Coverage Under Alternate Billing Arrangements

Occasionally, covered entity providers, i.e., providers who are covered individuals, bill directly for services provided to covered entity patients. This might occur when State Medicaid regulations prohibit a covered entity from billing for off-site and inpatient services or when the covered entity finds it financially impractical or disadvantageous to bill for off-site services. As a result, certain covered entities have used alternate billing arrangements for services provided by their covered employees or contractors to health center patients.

The most common alternate method of billing is for the covered individual to bill for the service and remit the funds received for that service to the covered entity. If an employee or contract provider, meeting all other requirements for coverage under FTCA, bills for a service delivered at a location not identified as a covered entity site within its approved Federal section 330 scope of project, FTCA coverage will apply to the provider and the covered entity as long as all of the following occur:

- The provider's employment contract authorizes the billing arrangements described above;
- The provider reports to the health center all such billings; and
- The funds received by the provider for the specific billing are transferred directly to the health center within a reasonable period of time.

If a claim is filed, the provider may be asked to sign a declaration affirming that the relevant funds were accordingly remitted to the health center (see **Section II: Claims and Lawsuits**).

F. FTCA Coverage When Responding to Emergency Events

F.1 Definition of Emergency

An emergency or disaster is defined, for purposes of this Manual, as an event affecting the overall covered entity target population or the covered entity's community at large, which precipitates the declaration of a state of emergency at a local, State, regional, or national level by an authorized public official such as a Governor, the Secretary of the U.S. Department of Health and Human Services, or the President of the United States. An emergency may be precipitated by such things as: hurricanes, floods, earthquakes, tornadoes, and widespread fires; civil disturbances; terrorist attacks; the collapse of structures within the community such as buildings and bridges; and infectious disease outbreaks or other public health threats.

In situations where an emergency has not been officially declared by a public official, HRSA/BPHC evaluates the situation on a case-by-case basis. The purpose of the evaluation is to determine whether extraordinary circumstances justify a determination that the situation, faced by a covered entity, constitutes an emergency for purposes of extending FTCA coverage under section 224 to services provided at temporary locations.

F.2 Scope of Project and FTCA Coverage

This section describes the two mechanisms by which, during an emergency, covered entities may include the provision of services at a temporary location within the Federal section 330 scope of project. The choice of which mechanism to use depends on whether the proposed activity is located (1) inside the covered entity's service area and within areas adjacent to the covered entity's service area such as neighboring counties, parishes, or other

political subdivisions, or (2) outside the covered entity's service area and beyond neighboring counties, parishes, or other political subdivisions.

F.2.1 FTCA coverage within the service area

FSHCAA and its implementing regulations do not permit FTCA coverage to follow covered individuals providing care outside of the covered entity's approved scope of project, which includes a defined target population and service area, or outside of the scope of their employment.

HRSA/BPHC recognizes that, during an emergency, covered entities are likely to participate in an organized State or local response and may be called upon to provide primary health care services at temporary locations. Temporary locations include any place that provides shelter to evacuees and victims of an emergency. Temporary locations also include those sites where mass immunizations or medical care is provided as part of a coordinated effort to provide a temporary medical infrastructure where it is needed the most.

FTCA coverage will apply to the performance of medical, surgical, dental, or related functions at temporary locations that have been approved within the covered entity's scope of project (see PIN 2008-01), if all of the following conditions are met:

1. Temporary locations are within the covered entity's service area or neighboring counties, parishes, or other political subdivisions adjacent to the covered entity's service area;
2. Services provided by covered individuals are within the covered entity's approved scope of project; and
3. All activities of covered individuals are conducted on behalf of the covered entity.

If covered individuals volunteer in their individual capacity to respond to an emergency, they will not be protected under FTCA.

Please note that State licensure requirements apply in all instances.

For purposes of FTCA coverage, patients served by covered individuals at temporary locations included in the covered entity's scope of project are considered the covered entity's patients. As such, the covered entity and its providers are covered by FTCA for services provided during the emergency at temporary locations.

F.2.2 FTCA coverage outside the service area

In rare cases, an emergency may impact an entire region or State, causing widespread devastation and evacuation of the population served by the covered entity. In these unique situations, a covered entity may be called upon to fulfill its requirements outside of its approved service area. Under the Health Center program, care may even need to be moved to a distant part of the State or region so that the displaced target population continues to be served.

In these instances, if the site of a covered entity in the impacted area is destroyed or unable to operate, the covered entity may submit a request for prior approval to temporarily change its scope of project to include operation of a temporary site within the covered entity's general geographic region, in an area outside the covered entity's regular service area and beyond areas adjacent to the covered entity's service area. The purpose of this scope change should be to provide medical care primarily to the covered entity's target population and to other medically underserved populations that are displaced by the emergency.

FTCA coverage will apply to services provided at temporary locations outside of the service area and in an area that is not in a neighboring county, parish, or political subdivision, that have been approved within the covered entity's scope of project (see PIN 2008-01), if all of the following conditions are met:

1. The covered entity must demonstrate that the purpose of the temporary site is to provide services primarily to its original health center target population. The covered entity must demonstrate that the population has been displaced by the emergency and that other displaced medically underserved populations may need their services as well;

2. Services provided are on a temporary basis;
3. Services are provided by covered individuals and are within the covered entity's approved scope of project; and
4. All activities of covered individuals are conducted on behalf of the covered entity.

Again, as noted in F.2.1, if covered individuals volunteer in their individual capacity to respond to an emergency they will not be protected under FTCA.

Please note that State licensure requirements apply in all instances.

F.3 FTCA Coverage for Non-Impacted Health Centers

In emergency situations, covered entities that are not directly impacted by the emergency may:

1. Assist at temporary sites within the covered entity's own service area and within neighboring counties, parishes, or political subdivisions; and
2. Operate temporary sites within the service area and within neighboring counties, parishes, or political subdivisions by including the temporary locations within the scope of project.

F.4 Non-Coverage of Volunteers Even in Emergencies

As stated in **Section I: B.5 Non-Covered Individuals**, FSHCAA does not extend FTCA coverage to volunteers at covered entities. The FSHCAA limitation of FTCA coverage to health center employees, governing board members, officers, and certain contractors applies to emergency situations.

While volunteers at covered entities will not be covered by FTCA under FSHCAA, it is possible that the volunteer would qualify for immunity or limited liability under State or Federal charitable immunity and limited liability statutes such as the Federal Volunteer Protection Act of 1997 or under Federal provisions related to the National Disaster Medical System [section 2811 of the PHS Act].

F.5 Emergency Related Examples

Below are additional examples of how the above requirements can be applied during an emergency.

F.5 Examples

Rendering Services Across State Lines - The underlying issue is not whether the provider has crossed state lines, but whether the covered individual is providing services within the covered entity's approved scope of project. If the covered entity's providers are providing care outside of the approved scope of project, the health center and providers are NOT covered by FTCA.

Border Areas - In certain border area cases, the covered entity's service area or neighboring counties may cross state lines. In this instance, if the covered individuals are providing care within the covered entity's approved scope of project, the entity and individuals are covered by FTCA.

Regional Emergencies - In regional emergencies, it may be possible for a covered entity to request prior approval to temporarily change its scope of project to include operation of a temporary site outside the state, as described in the sub-section, **F.2.2 FTCA coverage outside the service area**. Please note that state licensure requirements apply in all instances.

Operating at a Temporary Location Beyond 90 Days - Health centers expecting to operate at a temporary location beyond 90 days from the onset of the emergency must submit a request for a change in scope of project. Health centers are encouraged to submit the formal request well in advance of the 90 day limitation for a temporary site to allow for processing and to ensure FTCA coverage continues beyond the 90 days.

Temporary Sites and Scope During an Emergency - HRSA/BPHC will consider requests for the establishment of temporary sites in an emergency as part of the health center's scope of project if the relevant criteria described in

F.2.1 FTCA coverage within the service area or **F.2.2 FTCA coverage outside the service area** are met and the health center follows the process described. Note that prior approval is necessary for changes in scope described in **F.2.2 FTCA coverage outside the service area**. As stated earlier, health centers expecting to operate at a temporary location beyond 90 days from the onset of the emergency must submit a formal change in scope of project request.

Providing Services to Evacuees - If, as the result of an emergency, a covered entity provides services at a site within its scope of project to evacuees who have traveled from another service area where medical facilities have been destroyed, the health center and its providers are covered by FTCA for services to evacuees. For purposes of FTCA coverage, anyone seeking care at a covered entity's site, including at temporary sites within the scope of project, is a covered entity patient. It does not matter whether the person is a permanent or temporary resident of the community. Therefore, in the example above, FTCA coverage applies to the health center and its providers who provide services to the evacuees at its regular facility and at temporary sites.

Establishing a Temporary Site as a Result of Destruction to the Health Center - If a covered entity is destroyed as a result of a disaster and must continue to provide services at a temporary site and the site chosen is within the service area or within neighboring counties, parishes, or political subdivisions, medical services provided by the health center's staff at this temporary site are covered under FTCA.

As noted previously, HRSA/BPHC will consider a temporary site part of the health center's scope of project if the criteria described in **F.2.1 FTCA coverage within the service area** are met and the health center follows the process required. If a health center needs to continue operating a temporary site beyond 90 days from the onset of the emergency, the health center must submit a change in scope request.

Again, if a covered entity is destroyed as a result of a disaster, and in order to continue providing services, the destroyed covered entity sets up and operates a temporary site outside the service area in an area that is not in a neighboring county, parish, or political subdivision, medical services provided by the covered individuals of the covered entity at this temporary site are not covered under FTCA. In this situation, the process described in **F.2.1 FTCA coverage within the service area** is not applicable because the health center is providing services outside its service area and beyond neighboring counties, parishes, or political subdivisions. Instead, the health center should follow the process described in **F.2.2 FTCA coverage outside the service area** which applies to requests to temporarily change the scope of project to include operation of a temporary site outside the service area and beyond neighboring counties, parishes, or political subdivisions.

Assisting with Medical Response after an Emergency at a Temporary Location - In order to assist with the medical response after an emergency, covered individuals from a covered entity may work at a temporary location such as a shelter for evacuees within its service area or within neighboring counties, parishes or other political subdivisions adjacent to its service area. If temporary locations are included within the approved scope of project following the prescribed process in **F.2.1 FTCA coverage within the service area** the evacuees treated by those covered individuals are considered covered entity patients. Therefore, the health center and its staff are covered under FTCA for medical services provided to the evacuees.

Providing Care at a Local Hospital as Part of a Community-Wide Emergency Response - A covered individual that is providing care at a local hospital as part of a community-wide emergency response is covered under FTCA if the following conditions are met:

1. The **covered individual** is providing services within the covered entity's approved scope of project and service area; and
2. The **covered individual** is providing services at the direction of the covered entity (not volunteering on his/her own).

Volunteers that Provide Services During an Emergency - If health centers use volunteers to provide services during an emergency, then these volunteers are not eligible for coverage under the FTCA program. The relevant statute does not allow for FTCA coverage of health center volunteers. It is possible that the volunteer, if deployed

by the Federal Government as an intermittent Federal employee under a Federal Emergency Mission Act (FEMA) Mission Assignment, would be covered under another FTCA authority. It is also possible that the volunteer would qualify for immunity or limited liability under State or Federal charitable immunity and limited liability statutes such as the Federal Volunteer Protection Act of 1997 or the Federal provisions related to the National Disaster Medical System (section 2811 of the PHS Act).

G. The Deeming Application Process

FSHCAA requires a health center to apply for deemed status in order for FTCA coverage to be effective. The deeming application includes the program requirements for FTCA coverage including the health center's credentialing, quality improvement program, risk management systems, and past claims history.

HRSA/BPHC currently requires that all covered entities reapply for malpractice protection under the FSHCAA each year. Subrecipients are required to meet the same deeming requirements as the eligible health center. Consequently, each subrecipient is required to submit a deeming application annually, through a covered entity, in order to qualify for FTCA coverage. For up-to-date instructions on filing initial and renewal deeming applications, see <http://bphc.hrsa.gov/policiesregulations/policies/qualityrisk.html> for the applicable Program Assistance Letter.

To be deemed/covered under FSHCAA, an entity's deeming or redeeming application must provide sufficient documentation to verify that it:

- Has implemented appropriate policies and procedures to reduce the risk of malpractice and the risk of lawsuits arising out of any health or health related functions performed by the covered entity;
- Has implemented a system whereby professional credentials, references, claims history, fitness, professional review organization findings, and licensure status of its physicians and other licensed or certified health care providers are reviewed and verified and, where necessary, has obtained the permission from these individuals to gain access to this information;^[9]
- Has no history of claims having been filed against the United States as a result of the application of FSHCAA to the entity or its covered individuals, or, if such a history exists, has fully cooperated with the Department of Justice in defending any such claims and either has taken, or will take, any necessary corrective steps to assure against such claims in the future; and
- Will fully cooperate with the Attorney General and the Federal Government in providing the necessary information related to the claim.

G.1 Impact of Mergers and Acquisitions on Deeming

When two or more covered entities merge to form a new corporate entity, the new corporation must apply for FTCA coverage regardless if one or both were previously covered entities. No employee, contractor, or officer of the new corporation will have FTCA coverage until a deeming application from the new corporation is approved by HRSA/BPHC.

If a covered entity is absorbed by a non-deemed health center, meaning the legal entity remaining after the acquisition is the same legal entity that was not deemed, the staff from the deemed corporation will no longer be covered under FTCA. They become employees or contractors of a non-deemed corporation.

If a covered entity absorbs a non-deemed health center, the staff from the non-deemed center will be covered under FTCA if they meet all deeming requirements.

H. Insurance Considerations

FSHCAA provides a health center with the option of choosing to meet its malpractice liability protection through FTCA or the purchase of private insurance policies. Health centers that have chosen not to apply for, or have terminated FTCA coverage, may use Federal grant funds for the purchase of private malpractice insurance.

H.1 Dual Coverage

In general, dual coverage (i.e., both FTCA and private malpractice insurance covering the same activities) is not permitted. However, it is recognized that some health centers may have purchased malpractice insurance for health care practitioners with differing policy expiration dates as a means to stagger required tail insurance expenditures. In these situations, temporary dual coverage is allowable.

The combined use of FTCA and gap coverage (i.e., private insurance for activities not subject to FTCA coverage) is allowable. This can be accomplished by purchase of a policy for discrete activities or as a wrap-around (gap) policy that clearly delineates that coverage is only for activities not subject to FTCA coverage.

H.2 Subrogation

The U.S. Government may subrogate claims (i.e., pursue its right to receive payment for claims from private insurers) in instances where the covered entity has private coverage and a payment is made under FTCA for a covered activity (see **Section I: C. Covered Activities**). Upon payment of an FTCA claim, the U.S. Government is entitled to the extent of the payment covered under private insurance.

H.3 Gap Coverage

It is recognized that health centers may engage in non-covered activities (see **Section I: C. Covered Activities**) or may employ or contract with non-covered individuals (see **Section I: B. Covered Individuals**), thus creating gaps in malpractice protection for services/activities outside the Federal section 330 scope of project. Examples are services provided on behalf of the health center by volunteers or part-time contracted dentists. In these cases, covered entities may want to consider gap or wrap-around coverage to provide private insurance for activities not subject to FTCA coverage. Please note that while non-covered individuals are not covered under FTCA, the health center is still covered by FTCA as long as the activities are within the health center's scope of employment, which includes the scope of project. Non-covered individuals should be encouraged to secure insurance to cover activities not covered by the FTCA.

There are no restrictions on gap or wrap-around policies. However, covered entities should make sure that these policies clearly state that they do not cover activities approved for coverage under FTCA. This protects the health center from being in a situation of dual coverage for the same activity.

H.4 Other Insurance Considerations

FTCA provides protection only for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions, which constitute medical malpractice for purposes of this Manual. Consequently, even with FTCA coverage, covered entities will continue to need other types of insurance, such as non-medical/dental professional liability coverage, general liability coverage, director's and officer's liability coverage, automobile and collision coverage, fire coverage, and theft coverage.

SECTION II. CLAIMS AND LAWSUITS

I. Operation of FTCA for Health Centers

As previously discussed in this Manual, under FSHCAA, a section 330-funded health center, as well as its officers, directors, employees, and certain contractors, may be considered deemed to be Federal employees for the purpose of medical malpractice coverage under the FTCA (see **Section I: B. Covered Individuals**). As such, they are immune from personal liability for claims of medical malpractice arising from their deemed employment, contract for services, or duties as an officer or director of the deemed health center. Should they be sued in State courts for actions arising within the scope of this deemed employment, they should ensure prompt notification of the litigation to the U.S. Department of Health and Human Services (HHS) so that the action may be removed to Federal district court and the United States substituted as the named defendant. The covered entity and covered individuals will not be financially liable for any claims arising from their covered activities. However, this immunity does not preclude related actions by Federal, State and other licensing and certifying bodies. For example, immunity under FSHCAA will not preclude reporting of claims payments to the National Practitioner Data Bank or reporting to the applicable State licensing board, which may act to suspend or revoke a license to practice.

FTCA coverage is comparable to an occurrence type of malpractice policy (see **Section I: B.4 FTCA Protection/Protection for Covered Individuals**) and does not have a specific coverage limit with a monetary cap. Therefore, any coverage limits required by other organizations, such as hospitals, are met under FTCA. For example, a local hospital requirement of \$1 million per claim and \$3 million annual aggregate occurrence is met since FTCA would, as appropriate, provide for the payment of any damages awarded as a result of a settlement or judgment sums in excess of that amount. Under the FTCA, however, no punitive damages are allowed.

J. Overview of Claim Filings

The requirements for filing of an FTCA claim are found in federal law, federal implementing regulations, and federal case law. The FTCA is found at 28 U.S.C. § 1346(b), 2401(b), 2671-80.

To begin the process of filing an FTCA claim, a claimant must pursue the following:

- **Administrative Remedy:** A claimant must first seek an administrative remedy by presenting his or her claim to the HHS Office of the General Counsel (OGC), General Law Division (GLD), Claims and Employment Law Branch (CELB). Under the FTCA, if the claim is denied or a settlement is not reached within six months of such presentment, the claimant can sue the United States in the appropriate Federal district court. Alternatively, a claimant may request reconsideration of the denial of an administrative tort claim within six months after issuance of the denial.
- **Litigation:** Once an administrative claim has been denied by HHS, the claimant must file suit within six months in the appropriate Federal district court (or seek reconsideration by HHS/OGC) or the action will be time-barred. Cases are heard in Federal district court without a jury, and are defended by the Department of Justice (DOJ) with the assistance of HHS OGC.

Occasionally, a claimant erroneously files a lawsuit in State court in lieu of filing an administrative claim with HHS or less than six months after filing an administrative claim with HHS. These lawsuits are termed premature lawsuits.

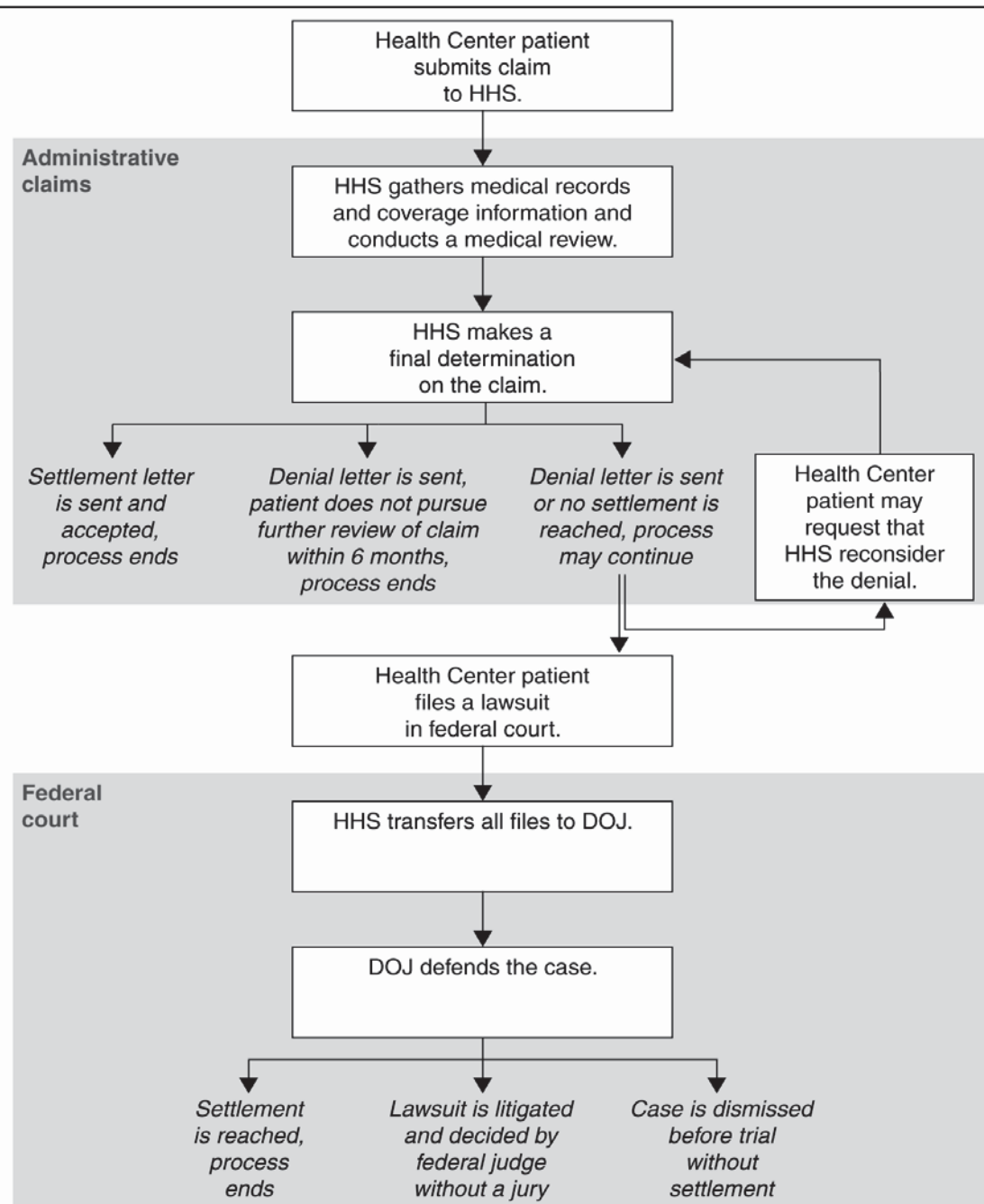
In the event that a claimant erroneously files a claim or serves premature lawsuit documentation directly with the health center, a covered entity should fax or e-mail a copy of the documentation to OGC/GLD/CELB at the address below:

U.S. Department of Health and Human Services
Office of the General Counsel
General Law Division
Claims and Employment Law Branch
U.S. Dept. of Health and Human Services
330 C Street, SW
Attention: CLAIMS
Switzer Building, Suite 2600
Washington, D.C., 20201
HHS-FTCA-Claims@hhs.gov
(202) 691-2369
202-619-2922 (fax)

With regard to premature lawsuits in which a claimant files a lawsuit against a covered entity in State court, the health center or its private counsel are strongly encouraged to make arrangements to obtain at least a 60-day extension from the state court to answer the complaint.

A covered entity representative should also immediately call or email OGC/GLD/CELB and ask to speak to any of the CELB FTCA attorneys for advice on how to proceed.

J.1 Federal Tort Claims Process for Deemed HRSA-Funded Health Center



K. Required Documentation for Claims Processing and Certification of Scope of Employment

The applicability of FTCA to a particular claim or case will depend upon verification by HHS OGC and/or certification by the United States Attorney, as appropriate, that:

1. The entity and individual are covered by the Act (see **Section I: A. Covered Entities and B. Covered Individuals**);
2. The covered individual was acting within the scope of employment;
3. The act or omission giving rise to the claim was within the approved scope of project of the covered entity; and
4. The act or omission giving rise to the claim occurred during the provision of services to covered entity patients and certain, limited non-health center patients (see **Section I: C. Covered Activities**).

Such certification or failure to certify is subject to judicial review.

The documents identified below are used by OGC/GLD/CELB to verify a covered entity's FTCA claim eligibility. The verification process confirms that the covered entity and the covered individuals were performing within the approved scope of project and scope of employment, contract for services, or duties as an officer or director of the covered entity pursuant to FTCA at the time of the incident in question.

Upon HHS OGC request, the covered entity must provide to HHS OGC, as applicable, required documentation, with tabs matching each of the individual items below and retain copies for filing. A covered entity should ensure that the dates of the documents correspond to the dates of the incident.

K.1 Required Documents for Premature Lawsuits and Claims Disposition

1. Three copies of the summons and complaint.
2. Three copies of the covered entity's initial deeming letter and all subsequent redeeming documentation including Notices of Grant Award (NGAs) containing re-deeming language or re-deeming letters, as appropriate.
3. Three copies of the covered entity's Federal section 330 grant application and Forms 5-A, 5-B and 5-C setting forth the approved scope of project including delivery sites and services, for the period of time covered by the claim.
4. Three copies of a statement, on covered entity letterhead, identifying which providers are involved or named in the claim and their dates of employment at the covered entity (if not already provided for a premature lawsuit relating to the same incident).
5. Evidence that the named providers were licensed physicians or licensed or certified health care providers at the time of the incident, including documentation of the specialty of all named providers.
6. In the event this alleged incident arises from acts or omissions that occurred outside of the covered entity's approved service sites, the name and address of the outside facility and information as to the nature of the affiliation between the outside facility, health center and its personnel.
7. Three copies of the Wage and Tax statements (W-2) for each individual involved in the alleged incident for the period of time covered by the claim.
8. If the provider whose care is at issue was a licensed or certified health care provider contractor at the time of the alleged incident, three copies of the 1099 form; an employment contract covering the period of the alleged incident; and evidence that the health care provider contractor was working full time, an average of 32.5 hours per week, or if employed part time, that the health care provider contractor was

providing services only in the fields of family practice, obstetrics and gynecology, general internal medicine or general pediatrics.

9. Three copies of a declaration verifying the employment of each individual involved in the alleged incident on the health center's letterhead, signed by each provider whose care is at issue. The declaration should state that to the best of his/her knowledge, the named provider was not billing privately, or, if the named provider was billing privately, he/she complied with the alternate billing arrangement requirements (see **Section I: E. Coverage under Alternate Billing Arrangements**). (Note: The health center should attempt to obtain a declaration from each named provider involved in the alleged incident; if the named provider is not available, the health center should document attempts to obtain the statement. The Chief Executive Officer (CEO) may sign the declaration only if all reasonable attempts have been made to obtain the statement from the named provider and documentation of these attempts is included with the CEO's declaration. The CEO's declaration should state that to the best of her knowledge, the named provider was not billing privately, or, if the named provider was billing privately, she complied with the alternate billing arrangement requirements.)
10. Three copies of any professional liability or gap insurance policy (see **Section I: H. Insurance Considerations**) that provides coverage to the health center and the named provider. The policies must cover the dates of the alleged incident. If neither the covered entity nor the named provider involved in the alleged incident has medical malpractice coverage other than that provided under FTCA, the covered entity should submit a statement on health center letterhead addressing that fact. However, if the named provider has purchased his/her own individual professional liability medical malpractice insurance coverage, which was in effect during the allegation time period, the covered entity must provide evidence of this coverage.
11. All correspondence received from the claimant pertaining to the claim.
12. The name and telephone number of a contact at the health center familiar with the certification information requested above.
13. Three copies of all of the plaintiff's medical records including x-rays, laboratory reports, and other results and treatments from the covered entity and any private facility that might be involved. (Note: The original medical records should be sequestered by the health center and retained until the conclusion of the case.)

Note: If a claim or lawsuit involving covered activities is presented or filed, it is essential that the covered entity preserve all potentially relevant documents. Once a covered entity or covered individual reasonably anticipates litigation—and it is reasonable to anticipate litigation once a claim or lawsuit is filed, whether administratively or in state or federal district court—the entity or individual must suspend any routine destruction and hold any documents relating to the claimant or plaintiff so as to ensure their preservation.

Additional and more detailed information regarding document retention will be provided after a claim or lawsuit is filed. However, covered entities should be aware of this requirement, act accordingly whenever a claim or lawsuit is filed, and seek further guidance from HHS OGC before destroying any potentially relevant documents.

L. Statute of Limitations

Under title 28, section 2401(b) of the FTCA, a claim must be presented within two years after the claim accrues. Generally, accrual occurs on the date of the injury. However, Federal case law also incorporates a discovery rule for determining claim accrual or starting date for the statute of limitations. Under the discovery rule, the statute of limitations commences when a person discovers, or in the exercise of reasonable care should discover, injury due to another's negligence. State statute of limitations periods do not apply to claims filed under the FTCA.

M. Medical Claims Review Panel (MCRP)

If a payment is made on an FTCA claim, the claim is then reviewed by the MCRP to identify the providers and to determine whether the standard of care was met for purposes of reporting to the National Practitioner Data Bank (NPDB). It should be noted that MCRP is administered by the Office of the Secretary.

N. Other Considerations within the Litigation Process

N.1 Litigation of FTCA Cases

Malpractice claims filed against the Public Health Service under the FTCA are handled by HHS OGC and DOJ. The delegated authority for the HHS lies with the General Law Division's CELB, whose FTCA attorneys are experienced in medical malpractice tort law.

DOJ is responsible for the defense of all litigation arising from acts or omissions covered under the FTCA. Within DOJ, a case ordinarily is assigned to a U.S. Attorney's Office where it is handled by an Assistant U.S. Attorney, with litigation support from HHS. In addition, DOJ Torts Branch attorneys may provide guidance to U.S. Attorney's Offices in consultation with attorneys from HHS OGC.

N.2 Health Centers Dissatisfied with their Representation

Cases filed under the FTCA are brought against the United States, not the covered entity. The defense of these cases is handled by the Assistant U.S. Attorney for the particular district. If there are perceived problems with representation, the covered entity should contact HHS OGC.

O. Subpoenas and Other Requests for Testimony

This section provides information concerning the handling of subpoenas and other requests directed to covered entities and individuals to provide testimony in medical malpractice litigation in which neither the employee, the health center, nor the United States is a party.

O.1 Background

Physicians and other employees of covered entities may be requested to provide testimony in litigation in which neither they nor the U.S. is a party. This happens primarily in the following two situations:

- The health center and/or the physician being subpoenaed was named as a defendant in a medical malpractice lawsuit. After the HHS OGC determined that FTCA applied and the suit was removed by the U.S. Attorney's Office to Federal court, the health center or physician was dismissed from that suit because the plaintiff failed to exhaust the required administrative remedies under FTCA.
- While the FTCA administrative claim is pending, the State lawsuit continues against other defendants, such as a local hospital and non-health center physicians. Neither the health center nor the physician being subpoenaed has been made a defendant in a medical malpractice suit to date. However, the physician likely will be asked to testify about health care that he/she provided to the injured plaintiff, who may then decide to include the physician and health center as new defendants.

In either situation, the health center and subpoenaed employee should have legal representation, and the Federal Government may have a strong interest in participating in that representation.

O.2 Procedure

The HHS Touhy regulation (45 CFR Part 2)(2008) prohibits Federal employees from giving testimony without prior approval by the appropriate Agency head, in this case the HRSA Administrator. The regulation applies to current and former employees and qualified contractors of covered entities with respect to testimony for medical malpractice tort litigation that relates to the performance of medical, surgical, dental, or related functions performed while the entity and its covered individuals were covered by FSHCAA. The Touhy regulations do not apply, in pertinent part, in the following situations:

- Any civil or criminal proceedings where the United States, the Department of Health and Human Services, and any agency thereof, or any other Federal agency is a party.
- Employees making appearances in their private capacity in legal or administrative proceedings that do not relate to the Department of Health and Human Services (such as cases arising out **of traffic accidents, crimes, domestic relations**, etc.) and not involving professional and consultative services.
- Any civil or criminal proceedings in State court brought on behalf of the Department of Health and Human Services.

In order to determine if the Touhy regulation applies to a specific health center provider and to facilitate representation by DOJ in appropriate medical malpractice cases, health centers should immediately fax subpoenas and any other requests for testimony of covered entities or individuals, including contractors who may qualify for FTCA coverage, to HHS OGC CELB.

HHS OGC conducts an inquiry into the matter to determine whether the subpoenaed individual was a covered individual acting within the scope of employment and within the covered entity's scope of project during the applicable time period. The OGC also determines if the act or omission giving rise to the claim occurred during the provision of services to the covered entity's patients or, in certain, limited situations, non-health center patients. Accordingly, HHS OGC responds to the inquiry by asking the health center to provide supporting documentation for the determination, if not already done in the case.

If HHS OGC determines that the subpoenaed individual has been acting in his/her capacity as a deemed federal employee, that individual is also covered by the Touhy regulation. HHS OGC will notify the health center or provider of its determination and will make a recommendation to the HRSA Administrator. If the Administrator determines that the request for testimony is proper and the testimony is authorized, HHS OGC contacts the appropriate U.S. Attorney to determine if representation by DOJ is necessary.

If the HRSA Administrator denies approval for the health center provider to comply with a subpoena for testimony, or if the HRSA Administrator does not act by the deadline, the health center provider must:

1. Appear at the stated time and place unless advised by OGC that responding to the subpoena would be inappropriate;
2. Produce a copy of the Touhy regulations; and
3. Respectfully decline to testify or produce any documents on the basis of the regulations.

SECTION III. APPENDIX

FTCA Contact Information

Category	Contact Information
Covered Entities Covered Individuals Covered Activities	If you have process-related questions, general requirement questions, or questions about whether an activity, individual, or entity is covered under the FTCA, please contact the BPHC helpline at 877-974-BPHC (877-974-2742). Hours of operation: 9:00 AM to 5:30 PM (ET).
Coverage under Alternate Billing Arrangements	If you have general questions on coverage under alternate billing arrangements, please contact the BPHC helpline at 877-974-BPHC (877-974-2742). Hours of operation: 9:00 AM to 5:30 PM (ET).
Deeming / Application Process	For information and/or questions on the FTCA initial or renewal deeming application process, please contact the BPHC helpline at 877-974-BPHC (877-974-2742). Hours of operation: 9:00 AM to 5:30 PM (ET).
Claims and Lawsuits	<p>Health centers must immediately fax or submit the necessary documents upon receipt and confirm receipt of all documents transmitted to the HHS Office of the General Counsel. To submit a claim or complaint filed in State court against the health center or staff, the appropriate information should be transmitted to the:</p> <p>U.S. Department of Health and Human Services Office of the General Counsel General Law Division Claims and Employment Law Branch U.S. Dept. of Health and Human Services 330 C Street, SW Attention: CLAIMS Switzer Building, Suite 2600 Washington, D.C., 20201 Phone: (202) 691-2369 Fax: 202-619-2922 (fax) HHS-FTCA-Claims@hhs.gov</p>

Category	Contact Information
Subpoenas and Other Requests for Testimony	<p>Immediately fax subpoenas and any other requests for testimony and confirm receipt of all documents emailed or faxed to:</p> <p>U.S. Department of Health and Human Services Office of the General Counsel General Law Division Claims and Employment Law Branch U.S. Dept. of Health and Human Services 330 C Street, SW Attention: CLAIMS Switzer Building, Suite 2600 Washington, D.C., 20201 Phone: (202) 691-2369 Fax: 202-619-2922 (fax) HHS-FTCA-Claims@hhs.gov</p> <p>Health centers should confirm receipt of all documents that they email or fax.</p>

[1] Here and throughout the PIN, “health center” refers to all organizations funded under section 330 of the PHS Act, including Community Health Centers, Migrant Health Centers, Health Care for the Homeless Health Centers, and Public Housing Primary Care Health Centers, and their properly qualified subrecipients.

[2] This authority may be further delegated.

[3] Deeming also provides additional protections under subsections 224(a) and 224(b) of the PHS Act.

[4] The term “subrecipient” is defined at 42 CFR 6.3 exclusively for purposes of FTCA coverage under FSHCAA.

[5] Subrecipients must meet the same deeming requirements as the covered entity and must submit a separate deeming application annually to HRSA to qualify and be approved for FTCA coverage.

[6] See PIN 2001-16: Credentialing and Privileging of Health Center Practitioners and PIN 2002-22: Clarification of Bureau of Primary Health Care Credentialing and Privileging Policy Outlined in Policy Information Notice 2001-16, both are available online at <http://bphc.hrsa.gov/policiesregulations/policies/qualityrisk.html>.

[7] Section 7 of the FSHCAA requires, under penalty of losing Medicare and Medicaid reimbursement, managed care plans to accept FTCA as the malpractice coverage for deemed health centers.

[8] Generally, subsection 224(i) of the PHS Act states that the Attorney General, in consultation with the Secretary, after notice and opportunity for a full and fair hearing, that an individual physician or other licensed or certified health care practitioner who is an officer, employee, or contractor a deemed entity is not considered an employee of the Public service, if it is determined they will expose the Government to a high risk of loss. The section also includes a non-exhaustive list of factors that may lead to this determination.

[9] See PIN 2001-16: Credentialing and Privileging of Health Center Practitioners and PIN 2002-22: Clarification of Bureau of Primary Health Care Credentialing and Privileging Policy Outlined in Policy Information Notice 2001-16, both are available online at <http://bphc.hrsa.gov/policiesregulations/policies/qualityrisk.html>.